ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE

Location of Meeting
Frontier Building, 3601 C Street, Room 890/896

FINAL MINUTES OF MEETING
October 13, 2006
8:00 a.m.

Committee Members Present:
Marvin Bergeson, MD
Heidi Brainerd, MS, RPh
Amber Briggs, PharmD
Richard E. Brodsky, MD
Robert Carlson, MD (telephonic)
Kelly Conright, MD
Lucy Curtiss, MD
Jeffrey G. Demain, MD
Traci Gale, RPh (telephonic)
Vincent Greear, RPh
R. Duane Hopson, MD
Thomas K. Hunt, MD
Diane Liljegren, MD (telephonic)
Andrzej Maciejewski, MD
Gregory R. Polston, MD
Janice L. Stables, MSN, ANP
Trish D. White, RPh (telephonic)

Committee Members Absent:
Ronald Keller, MD
Sherrie D. Richey, MD

Others Present:
David Campana, RPh
Melinda Sater, PharmD, First Health

1. Call to Order – Chair

The meeting was called to order at 8:04 a.m.

2. Roll Call

A quorum was present.

Mr. Campana noted that the agenda on the website was inaccurate. Other anti-depressants would be moved to the next agenda, but the scheduled public testimony would be heard. The website would be updated.

3. Public Comment – Local Public/Local Physicians

Dr. Jeff Sponsler: A Wasilla neurologist with sub-specialty training in epilepsy discussed pregabalin, trade name Lyrica, which has FDA approval for epilepsy and diabetic neuropathy. Some of his more difficult patients have had their lives disrupted by intractable seizures that are not well controlled by typical medications. Neurologists need a list of modern medications with fewer side effects to treat the more difficult patients. The older anti-epileptic drugs have major disadvantages, side effects and hidden costs. The newer medications, including Lyrica, are needed to treat these patients. These patients often have trouble finding employment so they are socially and economically dependent on society. They often have Medicaid insurance. As a neurologist, I see many patients that have neuropathic pain and diabetic neuropathy. These patients suffer from chronic pain. The treatment options for these disorders are lacking. The narcotic drugs used for treatment are habit forming, have abuse potential and are often street drugs. The non-steroidal analgesics have significant side effects such as renal toxicity and GI tract problems like stomach ulcers. Anti-epileptic drugs can provide the patient with relief without the adverse side effects. Lyrica is FDA approved for both epilepsy and diabetic neuropathy and is needed for these patients.

Dr. Brodsky pointed out that any drug could be prescribed by writing "medically necessary" on the prescription, so no patient would be denied a necessary medication.

Dr. Anne Morris: As a sleep disorder physician for 20 years, I feel the continuation of the open formulary rule for hypnotics is important. All the hypnotic drugs have advantages and disadvantages. Private insurers are making it difficult to prescribe hypnotic drugs for more than 15 days without preauthorization, although some patients need to be on them much longer. Private insurers are also requiring that physicians try drug A first, then drug B, etcetera. Making it hard for a physician to prescribe a drug increases the time involved for the physician and may decrease access to Medicaid. Keeping the open formulary rule will allow the physicians to give Medicaid patients better service.

Dr. Stilner: Thanked the committee for the most enlightened PDL in the United States. According to APA algorithms, Lamictal is the second mood stabilizer to be used after Lithium. It works very well for bipolar disorder patients and should be included on the PDL. As for antidepressants, Lexapro should be included on the PDL due to its non-racemic compound and superior side effect profile. Wellbutrin XL does not cause a switch into the manic pole in bipolar as much as the SSRIs. Due to Wellbutrin XL's dosage, it has better patient compliance. There is also less sexual side effect burden than the SSRI. Cymbalta and Effexor should both be included on the PDL. Cymbalta has shown documented benefits for diabetic neuropathy. For ADHD, Strattera should be included on the PDL. My sub-specialty is addiction. If someone is diagnosed with a history of methamphetamine dependence and ADHD, Strattera is preferred due to its non-dependency producing burden. He recommended adding Lamictal, Cymbalta, Effexor, Wellbutrin XL, Lexapro and Strattera to the PDL.

Dr. Ron Martino: A physician practicing neurology and psychiatry in Fairbanks, discussed the anticonvulsants. A broad number of anticonvulsants for the treatment of epilepsy should be included on the PDL. On the surface it may look like the anticonvulsants are the same, but that is very deceptive. He discussed the differences between Tegretol and Trileptal for various patients. Trileptal covers the same seizure spectrum as Tegretol, but it does not require blood monitoring, which makes it easier to treat patients who are in another location. Tegretol would treat a young adolescent's seizures adequately, however due to the risk for osteoporosis, Trileptal would be preferred. There is a question

about Depakote and polycystic ovarian disease and infertility, so Lamictal or Topamax may be preferred. Even though all the anticonvulsants appear to treat the same thing, they should be selected based on the patient's vulnerabilities to the side effects and individual needs. We need a broad and full spectrum of anticonvulsants to adequately treat individual patients, who will be on these medications for the rest of their lives.

Dr. Alex vonHafften: The formulary is not restrictive, because any drug can be prescribed by writing "medically necessary." Grandfathering patients on their previous medications will be increasing important as the PDL moves forward. The evolution of the behavioral pharmacy management system (BPMS), which is driven by clinical guidelines, may be the best way to improve psychiatric prescriptive practices. SSRIs are a class effect for therapeutic benefits and adverse side effects, but they are not therapeutically interchangeable. For SSRIs, Lexapro, paroxetine and fluoxetine should all be included on the PDL. In general, the longer acting medications are likely to have fewer side effects as well as fewer adverse side effects if a dose is missed. For the ADHD drugs, Strattera should be included on the PDL, because it is less likely to cause tolerance independence. In the amphetamine and methamphetamine class, a long acting, short acting, mixed salt and a single anima should be included. All the drugs in the sedative/hypnotic class have a role, but it is important to have non-benzodiazepines available. Drugs that assist sleep onset as well as sleep maintenance should be included. For the anticonvulsants, Lithium is the most lethal medication a psychiatrist prescribes. It can be very effective, but it has quite a few negative adverse side effects. Valproic, carbamazepine, lamotrigine, oxcarbazepine, and topiramate should be included on the PDL.

Dr. David Sampson: Nurse practitioners, physician assistants and physicians in Alaska have voiced concerns over the "medical necessity" rule and feel it should not require an inordinate amount of explanation. Patients with depression, anxiety disorders and psychiatry disorders have a terrible time with adherence, because they forget to take their medications. Anchorage has a very compromised support system for patients. The community mental health system has decreasing funding, which means we have fewer nurses, case managers and resources to make sure our patients stay on their medication. Programs are being dismantled and it is taking a toll. The following medications should be included on the PDL. Depakote ER, which is a once a day preparation, is instrumental in helping patients with schizophrenia and bipolar disorder. Topamax has a nice side effect profile including helping migraine headaches and weight loss. Lamictal is one of the few drugs approved for bipolar maintenance, it has a good side effect profile and it can be dosed once a day. Carbamazepine is possible for once a day dosing. In the antidepressant category, Cymbalta, Effexor XR and Wellbutrin XL are all once a day preparations that are highly effective. Strattera should be included on the PDL, because it is an excellent alternative for addiction prone people with adult ADHD.

4. Re-review of ADD/ADHD Medications

Dr. Beverly Hendelman: Dr. Hendelman, a child psychiatrist for over 30 years, felt the stimulants and non-stimulants for ADHD should be kept as open as possible. Focalin XR, Strattera and Provigil are all very helpful with children. Children often have side effects to medications and Native children react differently than Caucasian children. We have such a variety that we need as many choices as possible. One of the reasons I came to Alaska was the fact that I still had the ability to practice medicine. Physicians do not always have the time to get alternative medications authorized. Focalin short acting is often my first choice. If there are side effects, it stops as soon as possible and then I can

make other choices. I like Focalin XR, because of the way the medication works. Strattera is an excellent drug and works well for autistic children. Because of our ability to experiment with these drugs, we have more choices to effectively treat these children so they can function as normally as possible.

Dr. Bergeson said the FDA turned down the application for Provigil to be used on children.

Dr. Hendelman said Provigil could be used for mildy hyperactive children, not extremely hyperactive children. For children with severe ticks who are not responding to Strattera, Provigil works quite effectively. Adults with an abuse history also do well on Provigil.

Ms. Brainerd asked if Dr. Hendelman could cite any biochemical or pathological differences that would affect the way Native children, versus Caucasian children, reacted to the medications.

Dr. Hendelman said the statement was based on her 30 years of clinical experience working with children all over the world. For example, when she worked in New Zealand, the Native children there did not respond the same as the Caucasian children either.

Dr. Joe Schwab: Focalin XR is dosed once a day and has proven efficacy up to 12 hours. The formulation provides a biomobile release that emulates BID dosage. The immediate release portion represents 50% of the dose then four hours later the balance is released. This preparation is the only methylphenidate that is approved for use in children, adolescents and adults with ADHD. It is currently available in 5, 10, 15 and 20-milligram capsules. There have been several trials and studies done on Focalin XR. It is important to have a variety of these drugs available for the physician to treat patients. Children benefit from Focalin XR, because it has a very rapid onset of activity. Many times in ADHD children, one of the parents also have ADHD, and this medication can be used to treat both of them. A variety of drugs should be included on the PDL and Focalin XR should be one of them.

Dr. Judi Profant: Concerta offers a full 12 hours of efficacy. It has been shown to treat patients with ADHD as well as conduct disorder. It has been shown to not only improve the core symptoms, but also improved parent interactions. Last month there was an article published comparing the efficacy for driving simulation in adolescents who were treated for ADHD and driving was improved as compared to the other classes of stimulants.

Dr. Jeff Hille: Strattera should be included on the PDL for Medicaid patients in Alaska. When you look at ADHD, not all patients are the same. Up to 65% of patients have at least one co-morbid condition. Not all ADHD medications are the same. One size does not fit all in the treatment of ADHD. Not all patients respond the same. Some medications may not be appropriate for patients based on their co-morbid medical profiles. Strattera is unique in that it is the only non-stimulant medication available for the treatment of ADHD. As such, it fills an important therapeutic need in the treatment of this disorder. For example, co-morbid ticks are present in up to 11% of ADHD patients. Stimulant medications may worsen ticks and are contraindicated and/or have precautions against use in patients with this co-morbidity. Strattera does not have a contraindication for patients with co-morbid ticks. In a study of ADHD and co-morbid tick disorders, Strattera did not worsen or exacerbate ticks. Co-morbid anxiety disorders are present in 25-50% of ADHD patients. Stimulant medications are contraindicated in patients with agitated states and anxiety. Strattera is not contraindicated in these patients. In a study of ADHD and co-morbid anxiety, Strattera improved symptoms of ADHD as well

as symptoms of anxiety in those patients. Co-morbid substance use disorders may be present in up to 20% of ADHD patients. Many clinicians are reluctant to prescribe stimulants, because of their potential for abuse, diversion and misuse. Stimulants are controlled substances and should be used cautiously in patients with a history of alcohol or drug abuse. Strattera is not a controlled substance and has been proven to lack abuse liability. As such, Strattera may be a preferred agent in patients with a history of alcohol or substance abuse. There are a number of important factors to consider when making treatment decisions and decisions about the available of ADHD medications. It is important to also consider that up to 30% of patients may not respond to stimulant therapy. All these factors support the need for a broad availability of ADHD medications as well as Strattera on the PDL.

Dr. Sater gave the First Health presentation stimulants and related agents. There are seven available chemical entities. Provigil does not have a pediatric indication. Strattera has a unique mechanism of action that is a non-stimulant mechanism. These drugs are used in both adults and children with about 15% of the claims being for adults. In Alaska in September, we paid 1,896 claims for drugs in this class. In previous discussions, Drs. Bergeson and Hopson wanted to see all stimulants added to the PDL. Dr. VonHoften wanted to insure that a non-stimulant remained on the PDL. The motion was made to add all drugs to the PDL and the motion passed with four opposed. Since the last time this class was reviewed, Focalin XR was added to the market. The market share for this class is as follows: Concerta, 30%; Adderall XR, 18%; Strattera, 16%; Focalin XR, 6%; generic amphetamine salt combination, 5.5%; generic methylphenidate, 5%; and every other drugs in this class has less than 5%.

In response to Dr. Curtiss, Dr. Sater said there were two claims for the patch.

Dr. Bergeson said he would like to see both a short-acting and long-acting stimulant included on the PDL. Some people feel Focalin may have fewer side effects than Concerta, but the literature does not support that at this time. Strattera is a nice option for parents who do not want their child put on a stimulant. There are other non-stimulants used for ADHD, but they are not as effective as Strattera. This is a classification where grandfathering will be important due to the time required to stabilize a patient on these drugs.

Dr. Sater said Dr. Batista prefers Concerta to Strattera, because Strattera seems to agitate children more. Her other choice for treatment ADHD is Adderall.

Dr. Hopson agreed that it was very difficult to find the right medication for ADHD children. You often end up using combinations. It is important to have a wide variety of drugs available. Strattera and Concerta are the most popular choices. Focalin in both the immediate preparation and extended release should also be included.

Dr. Bergeson said some physicians added Strattera to Concerta or Adderall, because you can lower the amount of the stimulant. Methamphetamine should be excluded from the PDL, because of its addictive qualities. Not all the drugs are equal in their duration of action. The long-acting drugs work very well for children who are in school. A short-acting drug is useful to help them with their homework, but if you add another long-acting drug, they cannot sleep at night. Some people recommend using Focalin 24 hours a day, because it does not affect sleep.

Dr. Liljegren suggested including both a long-acting and short-acting methylphenidate product, plus Concerta, to the PDL.

Dr. Brodsky said the evidence shows that none of the drugs are superior. Although long-acting and short-acting drugs may be convenient and have compliance issues, they are not superior. The Institute of Medicine for Healthcare Improvement would say that variation leads to decrease in quality and increased costs in healthcare delivery. We do not have enough evidence here to make hard choices.

DR. LILJEGREN MOVED THAT THERE BE A SHORT- AND LONG-ACTING AGENT FOR METHYLPHENIDATE, INCLUDING CONCERTA, MIXED AMPHETAMINE SALTS AND DEXMETHYLPHENIDATE; AND INCLUDE STRATTERA. A GRANDFATHER CLAUSE WOULD BE ADDED FOR THIS CLASSIFICATION. DR. BERGESON SECONDED.

Mr. Campana explained how the grandfathering clause would work. Anyone who received medication in the last 60 days that was not on the PDL would be grandfathered and could get the medication without the medical necessity clause.

Dr. Sater pointed out that in the conclusion of the literature, the American Academy of Pediatric and Clinical Practice Guidelines says research to date has not shown clear advantages of one stimulant medication over another or between doses of a given agent. Based on review and analysis of clinical evidence, the stimulants are equally effective for this group.

The committee discussed the wording of the motion and whether dextroamphetamine should be excluded from the PDL. Dr. Sater said there were was a generic long-acting dextroamphetamine and there were about 50 claims a month for those drugs. Dr. Polston asked if a generic medication could be excluded. Dr. Brodsky said it could be excluded, but he wondered why they would want to. Question was called on the motion.

THE MOTION PASSED WITH THREE OPPOSED.

5. Re-review of the Hypnotic Medications

Dr. Jon Sonoda: The NIH had a universal consensus that insomnia can be chronic and may require maintenance drugs, which is different than how we looked at insomnia in the past. Patients who do not get adequate sleep have an increased chance of more complications of co-morbid disorders, including weight gain and chronic illnesses like asthma and diabetes. There is a lot of data on seasonal sleep and weight patterns that occur in Alaska. Many of the drugs that are being used for this are not approved or the best choice. We want to maintain sleep architecture, which the non-benzodiazepines promote. Ambien CR is approved for sleep maintenance and provides longer sleep. When you stop taking Ambien CR after six months of therapy, there are no withdrawal symptoms.

Dr. Gary Dawson: Rozerem is indicated for the treatment of insomnia characterized by difficulty with sleep onset. It is the first prescription insomnia medication with a new mechanism of action in the last 35 years. It works by specifically targeting the melatonin one and melatonin two receptors in the CNS. The MT1 receptor is thought to regulate sleepiness, whereas MT2 receptors are thought to be involved in circadian regulation. Rozerem does not work by CNS depression nor does it have an affinity for GABA, dopamine, serotonin, histamine, or opiate receptors. Rozerem's safety profile has been established across both adult and elderly patients in over 4,000 patients. It is not a controlled

substance and is the first, and only, non-scheduled hypnotic that is FDA approved for the treatment of insomnia. In assessing abuse liability of sedatives using doses 20 times the recommended dose, Rozerem did not differ from placebo in subjective drug liking, drug strength or street value. It was no different than placebo in cognitive and behavioral assessments. It has shown no evidence of rebound insomnia or withdrawal symptoms upon discontinuation and is approved for long-term use. The most common side effects are headaches, dizziness and fatigue, and these are only slightly increased over placebos. Efficacy has been established in adult and elderly populations and has been shown to be safe and efficacious in the reduction of sleep latency. It increased total sleep time across both adult and elderly patients in both transient and chronic insomnia models. It has one dose, 8 milligrams for all patients regardless of age. Rozerem offers a safe and efficacious alternative to using a controlled substance in the management of sleep onset insomnia.

Dr. Mike Herman: Lunesta was the only long-term drug mentioned in the NIH consensus statement. We have done two six-month studies, with up to 800 patients. Lunesta puts people to sleep very quickly and we keep people asleep all night. Most people do not have problems falling asleep, but with the maintenance component. Lunesta improves total sleep time up to 90 minutes in these trials. We have data looking at co-morbid conditions such as depression, menopause and others. Improving sleep can do a lot to help these other medical conditions. After six months of continuous use, patients were able to stop using Lunesta and maintain their level of performance. Lunesta is a very safe and efficacious drug that puts people to sleep and keeps them asleep.

Dr. Beverly Hendelman: Child psychiatrists do not like to use a lot of the new medications early on. With sleep being a major component of the problem in adolescents, I have initiated the use of Rozerem and found it very effective. I do not like to use anything addictive, because there is too much potential for abuse related to sleep. The Rozerem is effective, but not addicting.

Dr. Sater gave the First Health presentation on sedative/hypnotics. There are 10 available entities. There are extended and immediate release formulations. Last time, the committee divided this class into two classifications, benzodiazepine agents and non-benzodiazepine agents. Rozerem is a unique mechanism in this class. In September, in Alaska, there were 1,062 claims in this class. Previously, the benzodiazepines and non-benzodiazepines were considered separately with the committee agreeing that at least one agent from each group should be added to the PDL. Motions were made to add temazepam and zolpidem as preferred agents. Both motions passed unanimously. Since the last time this class was reviewed, Ambien CR, Lunesta and Rozerem have been added to the marketplace. Dr. Hopson stated that approximately 90% of the sedative hypnotic use in his practice is temazepam, although some Ambien is also used. The market share were as follows: Ambien, 40.4%; temazepam, 16%; Ambien CR, 15%; Lunesta, 14%; Rozerem, 10%; and the rest were under 3%.

Dr. Bergeson said pediatricians do not generally use this class. We are starting to use Rozerem, because of its non-addictive profile and the fact that it works on the melatonin side. Our first choice had been Benadryl, which was disproved. Pediatricians commonly use over-the-counter Melatonin. If we want to go to something else, Clonidine is probably our number one choice, but children can wake up with a nightmare three to four hours later. This class is rarely used in pediatrics, although Rozerem will probably be used more and more.

Dr. Conright said for the geriatric population, she used triazolam 90% of the time, because it has a low side effect profile. It tends to not to be habit forming and works well. The second choice is Ambien.

The literature indicates that Rozerem is less effective in the elderly, although it seems to work well in the younger population.

DR. DEMAIN MOVED THAT AT LEAST ONE BENZODIAZEPINE AND ONE NON-BENZODIAZEPINE, AS WELL AS ROZEREM, BE ADDED TO THE PDL. SECONDED BY DR. POLSTON.

The committee discussed whether Ambien CR should be added to the PDL since Ambien received the largest market share in the classification. Dr. Sater said Ambien was a preferred agent in the last review. Dr. Hunt did not see a reason to add Ambien CR to the PDL.

MOTION PASSED UNANIMOUSLY.

6. Re-review of Selective Serotonin Reuptake Inhibitors (SSRIs)

Dr. Mike Delusia: Lexapro is currently indicated for both major depression and general anxiety disorders. In March of 2005, the International Journal of Clinical Psychiatry published a paper that was one of the first head-to-head comparisons of citalopram versus escitalopram, which he reviewed. Escitalopram has demonstrated better tolerability when compared to other SSRIs. In the pivotal trials required by the FDA, escitalopram proved to be both statistically and clinically superior when compared to placebo for all primary and secondary measures, as well as tolerability. When compared to other SSRIs or the SNRI class for major depression and general anxiety disorders, escitalopram has demonstrated equivalent or enhanced efficacy as noted in multiple clinical trials. However, tolerability and other adverse effects were much lower for escitalopram when compared to the dual acting agents. Lexapro is dosed once a day without regard to food and no dosage adjustment is necessary in mild to moderate renal insufficiency or in hepatic failure. Most patients begin on 10 milligrams and remain on that dose, although some may require an increased dose to 20 milligrams. These characteristics contribute to Lexapro's outstanding efficacy, excellent tolerability and safety. This leads to improved patient compliance and successful patient outcomes. Elderly patients, who often have complex multiple drug regimens, have excellent tolerability and efficacy when using Lexapro.

Dr. Sater gave the First Health presentation of SSRIs. There are six available chemical entities. There is one combination agent in this class. Efficacy is similar among all agents. In Alaska, in September, there were 2,816 claims for drugs in this class. The market share was as follows: generic fluoxetine, 28%; Lexapro, 26%; generic sertraline, 23%; generic paroxetine, 13%; and all the other products combined added up to about 10%. Previously, there was a lengthy discussion regarding the use of the medical necessity clause in this class. Most members were convinced of a class effect with regard to efficacy and adverse reactions. After many amendments, three motions were made. First was to accept the SSRIs as equivalent, which passed with two opposed. Second was to include at least three drugs on the PDL, which passed with four opposed. Third was to grandfather any patient previously stable on any drug in this class, which passed unanimously. Current preferred agents are generic fluoxetine, generic paroxetine, and Lexapro. Since the last time this class was reviewed, generic sertraline has come to the market. Dr. Hopson feels that there is a class effect in this class. Fluoxetine, sertraline and paroxetine are primarily used in his practice. Dr. Polston stated that he did not feel SSRIs are useful in the treatment of pain.

Dr. Liljegren said fluoxetine should be included on the PDL, because it is the only one with a pediatric indication. Grandfathering people in this category is extremely important.

Dr. Curtiss said patients have a wide variation in response to these drugs, even though the research says they are equivalent. Drug interactions need to be considered in working with geriatric patients and patients who are on a number of medications. Citalopram, Lexapro or sertraline are most commonly used in her practice.

Dr. Conright said citalopram should be included on the PDL due to its low side effect profile.

Dr. Sater said at the last review, a motion was made that sertraline be preferentially added to the PDL, but that motion was defeated. No motion was made to include any drug on the basis of fewer drug interactions.

Dr. Brainerd said there were several issues to talk about from a pharmacy standpoint including the pediatric indication, pregnancy and lactation concerns, and drug interactions. Fluoxetine should be preferred for pediatrics. Citalopram, Lexapro or sertraline should be included as well.

Dr. Bergeson said fluoxetine had three products, two of which are generic, and one of them would probably be on the PDL no matter what decision is made.

Dr. Demain said the committee could say that one should be a liquid for children.

Dr. White asked if sertraline, as a generic, would automatically be included on the PDL. Dr. Brodsky none of the drugs were automatically added to the PDL. Dr. Sater said as a general rule of thumb when new generics come to the market, the likelihood that they will not be added immediately is very high. As the market levels out and a generic is on the market longer, the likelihood is higher that it will be added.

In response to Dr. Hunt, Dr. Sater said if the motion does not specify brand name Zoloft for the PDL then it will be added whenever it becomes cost effective to do so. Motions should be as broad as possible so there is more flexibility.

DR. HUNT MOVED TO INCLUDE AT LEAST THREE SSRIs, ONE OF WHICH MUST BE CITALOPRAM, ESCITALOPRAM OR A SERTRALINE PRODUCT; AND THAT A LIQUID FLUOXETINE BE AVAILABLE. AND A GRANDFATHER CLAUSE BE INCLUDED. SECONDED BY DR. HOPSON.

Dr. Liljegren requested that a fluoxetine be guaranteed for pediatric patients without specifying the form. Dr. Sater said the proposed motion would guarantee three drugs, at least one of which would be fluoxetine.

MOTION CARRIED WITH ONE OPPOSED.

7. Re-review of Other Antidepressants

Dr. Brodsky noted that testimony would be taken on the classification, but no voting would take place and it would be placed on next month's agenda.

Dr. Alexander VonHoften: This is a heterogeneous group and it is difficult to see this as a single class in making decisions. He reviewed several of the medications. Bupropion, the SNRIs and traxodone are essential medications. Mirtazapine and nefazodone could be medical necessity. The long-acting preparations have the advantage of fewer side effects and single day dosing, and that is most pertinent to Wellbutrin XL.

Dr. Brodsky noted that additional testimony would be taken at next month's meeting.

8. Re-review of Anticonvulsants, First and Second Generation

Dr. David Gross: Lyrica is the first and only product to carry the broad therapeutic indications of adjunctive use in the treatment of adults with partial onset seizures and neuropathic pain associated with diabetic peripheral neuropathy. Lyrica has proven to be safe and efficacious, as demonstrated in nine clinical studies. In epilepsy studies, Lyrica demonstrated the best in class responder rates with up to 51% of the patients having a greater than 50% reduction in seizure frequency. Lyrica has an excellent pharmacokinetics profile. It is well absorbed orally across the dosage range. It has linear and predictable pharmacokinetics, which leads to easier dosing. It has a low potential for clinically significant drug interactions with other AEDs, which is important because it is used as an adjunctive agent. It does not tend to show a dosage creep and 98% of the dosages prescribed in the last year have been 300 milligrams or less. Lyrica has a favorable side effect profile. Several studies and their outcomes were reviewed. Since the launch of Lyrica in the fall of 2005, there has been more than a 10% decrease in new prescription market share of the narcotic drug class in the treatment of painful neuropathies. The American Society of Pain Educators recently published treatment guidelines for DPN and considers Lyrica one of the four first line agents; only two of which have an approved indication for diabetic peripheral neuropathy pain. The American Academy of Neurology has placed Lyrica as a first line therapy for PHN. Lyrica should be considered as an important therapeutic option for the treatment of seizures and painful neuropathies and should be added to the PDL.

Dr. Joe d'Souza: (Indiscernible -- telephonic, difficult to hear.) Trileptal is used in the treatment of partial or generalized seizures. It has been available since 1990 and in the United States since 2000. It has a long and effective safety record. Trileptal has undergone extensive studies and evaluations. It can be taken with or without food and there is low significant weight gain during treatment.

Dr. Sater gave the First Health presentation on anticonvulsants, which would be divided into two sections. The older agents are carbamazepine derivatives. There are 10 available chemical entities. The mechanisms are not clearly understood for some of these drugs and vary widely, as do the adverse drug reaction profiles and efficacy for different therapeutic areas. In Alaska, in September, there were 1,960 claims for drugs in this class. The market share was as follows: Trileptal, 27%; Depakote, 17%; Depakote ER, 14.4%; generic carbamazepine, 9%; Dilantin, 8%; generic (indiscernible), 6; Tegretol XR, 5.5%; and the rest of the drugs amounted to about 12%.

Dr. Conright noted that many of these medications were used for very different conditions and questioned how the committee would approach the discussion. Dr. Brodsky reviewed a couple of ways the discussion could continue.

Dr. Liljegren felt the medications in this class should be grandfathered in.

The committee discussed which drugs should be included on the PDL.

Dr. Curtiss said for psychiatric purposes, making it simpler would help with adherence and felt that drugs that were long acting and did not include blood work should be included.

Dr. Demain suggesting including the carbamazephines, to include Trileptal since it has other unique indications.

Dr. Sater said Trileptal was frequently used because of the monitoring thing.

DR. DEMAIN MOVED THAT THE CARBAMAZEPINE GROUP WAS A CLASS EFFECT, BUT TRILEPTAL WOULD BE PREFERENTIALLY INCLUDED ON THE PDL.

Dr. Bergeson felt a chewable formulation should be included for pediatrics.

The committee again discussed how the category should be reviewed.

Dr. Brodsky said the committee seemed to like Trileptal, a long acting and pediatric form in the valproic acid group, and phenytoin.

Dr. Sater said Dr. Downs felt all of the drugs were necessary.

DR. DEMAIN MOVED THAT WITHIN THE CARBAMAZEPINE GROUP, A PEDIATRIC DELIVERY FORM AND AN ADULT FORM BE INCLUDED WITH TRILEPTAL OR OXCARBAZEPINE BEING PREFERRENTIALLY INCLUDED; IN THE VALPROIC ACID GROUP, A VARIED DOSAGE BE INCLUDED FOR ADULTS AND PEDIATRICS; AND A PHENYTOIN BE INCLUDED ON THE PDL. THE GRANDFATHER CLAUSE WOULD BE ESTABLISHED FOR THIS CLASSIFICATION. SECONDED BY DR. HUNT.

MOTION PASSED UNANINMOUSLY.

Dr. Sater reviewed the second-generation anticonvulsants. There are seven available chemical entities. A few of them are available as generic products. Mechanisms are drastically different between the agents. Adverse drug reactions and efficacy for different conditions are variable between the agents. In September there were 1,822 claims for drugs in this class. The market share was as follows: generic gabapentin, 33%; Topamax, 28%; Lamictal, 18%; Keppra, 9%; Lyrica, 6%; Gabitril, 3%; and less than 3% for the other agents.

Dr. Polston said Lyrica was a much easier drug to use and evaluate, and patients seemed to tolerate it well.

Dr. Hunt said he spoke with Susan Bertrand at the AA Pain Clinic and she urged us to consider keeping Lyrica on the PDL.

DR. BERGESON MOVED TO INCLUDE FOUR AGENTS, TO INCLUDE LYRICA. THE GRANDFATHER CLAUSE WOULD BE ESTABLISHED FOR THIS CLASS.

Dr. Curtiss said lamotrigine worked well in psychiatric practices for bipolar disorder and should be included on the PDL.

Dr. Brodsky suggested specifying which four drugs the committee wanted included on the PDL.

DR. BERGESON WITHDREW HIS MOTION.

DR. LILJEGREN MOVED THAT AT LEAST GABAPENTIN, (INDISCERNIBLE -- TELEPHONIC). THE GRANDFATHER CLAUSE WOULD BE ESBALISHED FOR THIS CLASS. SECONDED BY DR. GREEAR.

MOTION CARRIED UNANIMOUSLY.

Dr. Brodsky noted that the next meeting would be November 17, 2006.

9. Final Comments by Chair or Other Members

Dr. Sater reviewed the changes made to the PDL at this meeting.

- Stimulants: Adderall XR, generic amphetamine salt combination, Concerta, dextroamphetamine extended release and immediate release, Focalin, Metadate CD, Metadate UR, methylphenidate ER, methylphenidate generic, Ritalin LA, Strattera and Focalin XR will be preferred.
- Sedative/Hypnotics: Flurazepam, temazepam, triazolam, estazolam, Ambien CR and Rozerem.
- SSRI: Fluoxetine solution, fluoxetine generic, paroxetine generic and escitalopram generic.
- First Generation Anticonvulsants: Depakote ER; Depakote Sprinkle; ethosuximide generic in all forms; phenytoin generic, capsule and extended release; valproic acid, capsules and syrup; carbamazepine, chewable, suspension and tablets; Carbatrol; Equetro; Tegretol XR; Trileptal suspension and tablets.
- Second Generation Anticonvulsants: gabapentin; Gabitril; (indiscernible); Topamax; Lyrica; (indiscernible) capsules and syrup.

Dr. Sater will email the above list to the committee members.

Mr. Campana said the meeting minutes from the last meeting would be distributed, as well as being on the website, and would be approved at the next meeting.

Dr. Brodsky adjourned the meeting at 11:32 a.m.